#### UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION

MDL No. 1456

CIVIL ACTION: 01-CV-12257-PBS

Judge Patti B. Saris

THIS DOCUMENT RELATES TO State of Montana v. American Home Products Corp., et al., D. Mont. Cause No. CV- 02-09-H-DWM

#### GLAXOSMITHKLINE'S ANSWER TO STATE OF MONTANA'S SECOND AMENDED COMPLAINT

Defendant SmithKline Beecham Corporation d/b/a GlaxoSmithKline<sup>1</sup> ("GSK") hereby responds and answers the State of Montana's Second Amended Complaint (the "Complaint") as follows:

#### **Preface**

Prior to addressing the specific allegations of the numbered Paragraphs, GSK states the following general objections and responses to the Complaint as a whole. The Complaint contains purported quotations from a number of sources, many of which are unidentified. If any of the quotations originate in documents protected by the attorney-client privilege, the work-

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SmithKline Beecham Corporation, d/b/a GlaxoSmithKline, is one of the three defendants comprising the so-called "GSK Group" in the Complaint. Named defendant GlaxoSmithKline, plc, a foreign holding company, has not yet been properly served under the Hague Convention and no appearance has been made on its behalf. Named defendant Glaxo Wellcome, Inc. no longer exists, as it was previously merged into SmithKline Beecham Corporation to form SmithKline Beecham Corporation, d/b/a GlaxoSmithKline and, therefore, no appearance has been entered on its behalf either. DC: 1479279-1

product doctrine or the joint-defense privilege, GSK reserves the right to assert such privileges, hereby moves to strike such references and demands return of any such documents that Plaintiff may have in its possession, custody or control. In answering allegations consisting of quotations, an admission that the material quoted was contained in a document or was uttered by the person or entity quoted shall not constitute an admission that the substantive content of the quote is or is not true or that the material is relevant or admissible in this action.

The Complaint also improperly and repetitively refers to GSK and certain other defendants and third parties on a collective basis, failing to plead with requisite particularity allegations against GSK. It also improperly mixes factual allegations with inflammatory rhetoric so as to make it virtually impossible to respond meaningfully. Finally, the Complaint includes terms that are undefined and that are susceptible of different meanings.

Notwithstanding these pleading deficiencies, GSK has attempted to respond to Plaintiff's allegations.. To the extent allegations refer to the knowledge, conduct or actions of other entities, GSK is generally without knowledge or information sufficient to form a belief as to the truth of those allegations and, on that basis, GSK denies those allegations. GSK also denies each and every allegation contained in the Complaint, except as specifically hereinafter admitted, and any factual averment admitted herein is admitted only as to the specific facts and not as to any conclusions, characterizations, implications, innuendos or speculations that are contained in any averment or in the Complaint as a whole. Moreover, GSK specifically denies any allegations contained in headings, footnotes, the Table of Contents or unnumbered Paragraphs in the Complaint. These comments and objections are incorporated, to the extent appropriate, into each numbered paragraph of this Answer.

#### I. <u>INTRODUCTION</u>

- 1. To the extent that the allegations set forth in Paragraph 1 contain Plaintiff's characterization of the action, no answer is required and none is made. GSK denies the remaining allegations in Paragraph 1 of the Complaint that pertain to it.
- 2. GSK admits that it is a manufacturer of pharmaceutical products. To the extent the allegations of this Paragraph refer to statutory or regulatory programs, the statutes, regulations and other sources regarding those programs speak for themselves, and any characterizations thereof are denied. To the extent the allegations in Paragraph 2 of the Complaint are directed to persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations and, therefore, denies those allegations. GSK denies the remaining allegations in Paragraph 2 of the Complaint that pertain to it.
- 3. GSK admits that prescription drugs can benefit patients through better overall health, avoidance of more expensive surgical procedures, and, in some cases, longer life. The remaining allegations in Paragraph 3 contain Plaintiff's generalizations and self-serving conclusions. Accordingly, no answer is required and none is made. To the extent an answer is deemed to be required, the allegations are denied and strict proof is demanded thereof.
- 4. The allegations in Paragraph 4 contain Plaintiff's generalizations and self-serving conclusions. Accordingly, no answer is required and none is made. To the extent an answer is deemed to be required, the allegations are denied and strict proof is demanded thereof.
- 5. GSK admits that some private and public drug reimbursement systems reimburse physicians and pharmacies based upon the AWP as published and reported by various compendia. GSK denies the remaining allegations in Paragraph 5 of the Complaint that pertain to it.

- 6. GSK admits that it has provided certain list prices to various commercial pricing compendia and believes that those compendia consider the information provided by GSK when publishing AWPs for GSK's products. GSK denies the existence of, and its participation in, any "AWP Inflation Scheme" as alleged in Paragraph 6 of the Complaint. To the extent the allegations in Paragraph 6 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. To the extent the allegations of Paragraph 6 contain legal arguments or conclusions of law, no answer is required and none is made. GSK denies the remaining allegations in Paragraph 6 of the Complaint that pertain to it.
- 7. GSK denies the existence of, and its participation in, any "AWP Inflation Scheme" as alleged in Paragraph 7 of the Complaint. To the extent the allegations in Paragraph 7 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. To the extent the allegations of Paragraph 7 contain legal arguments or conclusions of law, no answer is required and none is made. GSK denies the remaining allegations in Paragraph 7 of the Complaint that pertain to it.
- 8. GSK denies the allegations in Paragraph 8 of the Complaint that pertain to it. To the extent the allegations in Paragraph 8 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.

- 9. GSK denies the allegations in Paragraph 9 of the Complaint that pertain to it. To the extent the allegations in Paragraph 9 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.
- 10. GSK denies the allegations in Paragraph 10 of the Complaint that pertain to it. To the extent the allegations in Paragraph 10 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.
- 11. GSK admits that it entered into a Rebate Agreement with the Secretary of Health and Human Services. The remaining allegations in Paragraph 11 of the Complaint attempt to summarize statutes and regulations applicable to the Medicaid Rebate Program and therefore constitute legal conclusions to which no response is required. Pursuant to the Court's June 10, 2004 Order, all of Plaintiff's "Best Price" claims against GSK have been dismissed except those relating to Flonase and Paxil, as referenced in Paragraphs 617 through 620 of the Complaint. Those claims have been specifically released by Plaintiff in a separate Settlement Agreement and Release. Therefore, Plaintiff has no remaining "Best Price" claims against GSK in this Complaint.
- 12. GSK denies the allegations in Paragraph 12 of the Complaint that pertain to it. To the extent the allegations in Paragraph 12 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies

those allegations. Pursuant to the Court's June 10, 2004 Order, all of Plaintiff's "Best Price" claims against GSK have been dismissed except those relating to Flonase and Paxil, as referenced in Paragraphs 617 through 620 of the Complaint. Those claims have been specifically released by Plaintiff in a separate Settlement Agreement and Release. Therefore, Plaintiff has no remaining "Best Price" claims against GSK in this Complaint.

- 13. GSK denies the allegations in Paragraph 13 of the Complaint that pertain to it. To the extent the allegations in Paragraph 13 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.
- 14. GSK denies the allegations in Paragraph 14 of the Complaint that pertain to it. To the extent the allegations in Paragraph 14 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.
- 15. GSK denies the allegations in Paragraph 15 of the Complaint that pertain to it. To the extent the allegations in Paragraph 15 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.
- 16. GSK denies the allegations in Paragraph 16 of the Complaint that pertain to it. To the extent the allegations in Paragraph 16 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than GSK, GSK is without knowledge or

information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.

- 17. GSK denies the allegations in Paragraph 17 of the Complaint that pertain to it. To the extent the allegations in Paragraph 17 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.
- 18. The allegations set forth in Paragraph 18 contain Plaintiff's characterization of the action. No answer is required and none is made. To the extent an answer is deemed to be required, the allegations are denied and strict proof is demanded thereof.
- 19. GSK denies the allegations in Paragraph 19 of the Complaint that pertain to it. To the extent the allegations in Paragraph 19 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.
- 20. GSK denies the allegations in Paragraph 20 of the Complaint that pertain to it. To the extent the allegations in Paragraph 20 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.
- 21. The allegations set forth in Paragraph 21 contain Plaintiff's characterization of the action. No answer is required and none is made. To the extent an answer is deemed to be required, the allegations are denied and strict proof is demanded thereof.

- 22. The allegations set forth in Paragraph 22 contain Plaintiff's characterization of the action. No answer is required and none is made. To the extent an answer is deemed to be required, the allegations are denied and strict proof is demanded thereof.
- 23. The allegations set forth in Paragraph 23 contain Plaintiff's characterization of the action. No answer is required and none is made. To the extent an answer is deemed to be required, the allegations are denied and strict proof is demanded thereof.

#### II. PARTIES

- 24. GSK admits that Mike McGrath is the current Attorney General of the State of Montana. To the extent the allegations refer to statutes, regulations or other documents, those sources speak for themselves and are the best evidence of their contents. To the extent the allegations contain legal conclusions regarding the scope of the Attorney General's statutory authority, no answer is required and none is made. Any characterizations are denied. GSK denies the remaining allegations in Paragraph 24 of the Complaint that pertain to it.
- 25. GSK generally admits the factual allegations set forth in Paragraph 25 and avers that to the extent the allegations refer to statutes, regulations or other documents, those sources speak for themselves and are the best evidence of their contents. Any characterizations are denied. To the extent the allegations in Paragraph 25 set forth legal arguments or conclusions of law, no response is required and none is made.
- 26. GSK generally admits the factual allegations set forth in Paragraph 26 and avers that to the extent the allegations refer to statutes, regulations or other documents, those sources speak for themselves and are the best evidence of their contents. Any characterizations are denied. To the extent the allegations in Paragraph 26 set forth legal arguments or conclusions of law, no response is required and none is made.

- 27. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 27 and, therefore, denies those allegations.
- 28. GSK generally admits the factual allegations set forth in the first sentence of Paragraph 28 and avers that to the extent the allegations refer to statutes, regulations or other documents, those sources speak for themselves and are the best evidence of their contents. Any characterizations are denied. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in the second sentence of Paragraph 28 and, therefore, denies those allegations. To the extent the allegations in Paragraph 28 set forth legal arguments or conclusions of law, no response is required and none is made.
- 29. GSK denies the allegations set forth in Paragraph 29 of the Complaint that pertain to it. To the extent the allegations in Paragraph 29 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. To the extent the allegations in Paragraph 29 set forth legal arguments or conclusions of law, no response is required and none is made. To the extent an answer is deemed to be required, the allegations are denied and strict proof is demanded thereof.
  - 30. GSK admits that it conducted business in the State of Montana.
- 31-73. The allegations in Paragraphs 31 through 39 of the Complaint are directed to other defendants and require no response from GSK.
- 74. In response to Paragraph 74 of the Complaint, GSK admits only that GlaxoSmithKline, plc is a public limited company organized under the laws of England and Wales, with its principal place of business located at 980 Great West Road, Brentford, Middlesex, United Kingdom TW8 9GS, and that in December 2000, following shareholder and

judicial approval, GlaxoSmithKline, plc acquired Glaxo Wellcome, plc and SmithKline Beecham, plc pursuant to a Scheme of Arrangement. Except as so admitted, GSK denies the remaining allegations of this Paragraph. GSK specifically denies that GlaxoSmithKline plc had any involvement with the matters alleged in the Complaint. GSK further specifically denies that GlaxoSmithKline plc's "operational headquarters are located at One Franklin Plaza, 16<sup>th</sup> and Race Streets, Philadelphia, Pennsylvania."

- 75. GSK admits the allegations in Paragraph 75 of the Complaint.
- 76. GSK denies the allegations of Paragraph 76 of the Complaint. By way of further answer, GSK states that Glaxo Wellcome, Inc. was merged into SmithKline Beecham Corporation in March 2001 and no longer exists as a corporation.
- 77. In response to the allegations of Paragraph 77 of the Complaint, GSK admits only that Plaintiffs refer to GlaxoSmithKline plc, SmithKline Beecham Corporation, and Glaxo Wellcome, Inc. as "GSK Group" in the Complaint. Except as so admitted, GSK denies the remaining allegations of this Paragraph and incorporates its answers above concerning Glaxo Wellcome, Inc. and GlaxoSmithKline plc. GSK further states that Plaintiffs have failed to effect valid service of process on either GlaxoSmithKline plc or Glaxo Wellcome, Inc.
- 78. In response to the allegations of Paragraph 78 of the Complaint, GSK admits only that it is a pharmaceutical company. Except as so admitted, GSK denies the remaining allegations of this Paragraph. By way of further answer, the allegations in this Paragraph are directed to other defendants not properly served with valid service of process, and therefore require no response from GSK.
  - 79. GSK admits the allegations in Paragraph 79 of the Complaint.

80-111. The allegations in Paragraphs 80 through 111 of the Complaint are directed to other defendants and require no response from GSK.

# III. PRESCRIPTION DRUG SPENDING IN THE UNITED STATES HAS INCREASED DRAMATICALLY, DISPROPORTIONATELY IMPACTING THE POOR AND ELDERLY

- 112. The allegations in Paragraph 112 contain Plaintiff's generalizations and self-serving conclusions. Accordingly, no answer is required and none is made. To the extent an answer is deemed to be required, the allegations are denied and strict proof is demanded thereof.
- 113-121. The allegations set forth in Paragraphs 113 through 121 are alleged findings, opinions, statements or conclusions contained in the "Chartbook," "Chartbook Update" and "Fact Sheet" cited in Paragraphs 113 through 121 of the Complaint. GSK avers that those sources cited in Paragraphs 113 through 121 are the best evidence of their contents. GSK denies that Plaintiff has accurately characterized any alleged finding, opinion, statement or conclusion contained therein, or that such are applicable to GSK. GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations and demands strict proof thereof.
- 122. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 122 and, therefore, denies those allegations.
- 123. GSK denies the allegations set forth in Paragraph 123 of the Complaint that pertain to it.

#### IV. THE PRESCRIPTION DRUG MARKET

124-141. The allegations set forth in Paragraphs 124 through 141 contain Plaintiff's self-serving conclusions and generalizations regarding the Prescription Drug Market without specific detailed factual allegations averred against GSK. Accordingly, no answer is required and none is made. To the extent an answer is deemed to be required, the allegations are denied and strict

proof is demanded thereof. Moreover, the allegations set forth in Paragraphs 124 through 141 contain alleged findings, opinions, statements or conclusions from the "Chartbook." GSK avers that the Chartbook is the best evidence of its contents. GSK denies that Plaintiff has accurately characterized any alleged finding, opinion, statement or conclusion contained therein, or that such are applicable to GSK. GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations and demands strict proof thereof.

### V. GOVERNMENT REIMBURSEMENT SYSTEMS FOR PRESCRIPTION DRUGS

- 142. GSK admits the allegations set forth in Paragraph 142.
- 143. GSK admits the allegations set forth in Paragraph 143.
- 144. GSK admits the allegations set forth in Paragraph 144.
- 145. GSK avers that "Medicare Explained" cited in Paragraph 145 of the Complaint speaks for itself and is the best evidence of its contents. GSK denies that Plaintiff has accurately characterized any alleged finding, opinion, statement or conclusion contained therein, or that such are applicable to GSK. GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.
- 146. GSK admits that the reimbursement methodology for drugs covered by Medicare Part B is set forth at 42 C.F.R. § 405.517, which is the best evidence of its contents.
- 147. GSK denies the allegations in the first sentence of Paragraph 147 of the Complaint insofar as the source of the quoted material is unidentified. GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. GSK admits it is aware that providers of Medicare- and

Medicaid-covered products have historically been reimbursed based on AWP published in certain compendia.

- 148. GSK admits the allegations in Paragraph 148 of the Complaint.
- 149. GSK admits that the Medicare Program has publicly announced that it would use the AWP published in independently produced pricing publications as the basis for reimbursement. GSK states that the Program Memo AB-99-63 cited in Paragraph 149 of the Complaint is the best evidence of its contents.
- 150. GSK states that the Program Memo AB-99-63 cited in Paragraph 150 of the Complaint is the best evidence of its contents.
- 151. GSK admits that it has provided certain list prices to various commercial pricing compendia and believes that those compendia consider the information provided by GSK when publishing AWPs for GSK's products. To the extent the allegations in Paragraph 151 refer to the knowledge, conduct or actions of or benefits received by persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.
  - 152. GSK admits the allegations in Paragraph 152 of the Complaint.
  - 153. GSK admits the allegations in Paragraph 153 of the Complaint.
- 154-157. GSK avers that the sources cited in Paragraphs 154 through 157 of the Complaint are the best evidence of their contents. GSK denies that Plaintiff has accurately characterized any alleged finding, opinion, statement or conclusion contained therein, or that such are applicable to GSK. GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.

- 158. GSK generally admits the factual allegations set forth in Paragraph 158 and avers that to the extent the allegations refer to statutes, regulations or other documents, those sources speak for themselves and are the best evidence of their contents. To the extent the allegations in Paragraph 158 set forth legal arguments or conclusions of law, no response is required and none is made.
- 159. GSK generally admits the factual allegations set forth in Paragraph 159 and avers that to the extent the allegations refer to statutes, regulations or other documents, those sources speak for themselves and are the best evidence of their contents. To the extent the allegations in Paragraph 159 set forth legal arguments or conclusions of law, no response is required and none is made.
- 160. GSK generally admits the factual allegations set forth in Paragraph 160 and avers that to the extent the allegations refer to statutes, regulations or other documents, those sources speak for themselves and are the best evidence of their contents. GSK avers that the "Detailed Case Studies" cited in Paragraph 160 of the Complaint is the best evidence of its contents.
- 161. GSK is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 161 and, therefore, denies those allegations. GSK avers that the "Detailed Case Studies" cited in Paragraph 160 of the Complaint is the best evidence of its contents.
- 162. GSK admits that the reimbursement methodology for outpatient prescription drugs covered by the Montana Medicaid Program is set forth at Mont. Admin. R. 37.86.1101 *et seq.*, which is the best evidence of its contents. To the extent the allegations rely on the "Prescription Drug Program" cited in the last sentence of Paragraph 162, GSK avers that it is the

best evidence of its contents. GSK denies that Plaintiff has accurately characterized any alleged finding, opinion, statement or conclusion contained therein, or that such are applicable to GSK.

163. GSK admits it is aware that Medicaid beneficiaries are generally responsible, but not necessarily required, to pay a co-payment. To the extent the allegations refer to statutes, regulations or other documents, those sources speak for themselves and are the best evidence of their contents. Any characterizations are denied. To the extent the allegations in Paragraph 163 set forth legal arguments or conclusions of law, no response is required and none is made. GSK denies the remaining allegations in Paragraph 163 of the Complaint that pertain to it.

# VI. AWP PLAYS A CENTRAL ROLE IN ALL PRESCRIPTION DRUG REIMBURSEMENT SYSTEMS, AND THE TRUTHFUL REPORTING OF AWPS IS ESSENTIAL TO THE INTEGRITY OF THE MARKETPLACE

- 164. GSK admits that AWPs play a role in various prescription drug reimbursement systems that operate in the United States. GSK denies all other allegations set forth in Paragraph 164.
- 165. Upon information and belief, GSK admits the allegations in the first two sentences of Paragraph 165 of the Complaint. GSK denies all other allegations set forth in Paragraph 165.
- 166. GSK admits that various participants in prescription drug reimbursement systems rely on AWPs to reimburse physicians and pharmacies. To the extent the allegations in Paragraph 166 refer to the knowledge, conduct or actions of or benefits received by persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. GSK denies all other allegations in Paragraph 166.

- 167. GSK admits that independently produced compendia periodically report AWPs for prescription medicines sold in the United States. To the extent the allegations in Paragraph 167 refer to the knowledge, conduct or actions of or benefits received by persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. GSK denies the remaining allegations of Paragraph 167.
- AWPs for prescription medicines sold in the United States. GSK states that the 1999 edition of the *Red Book* and the June 1996 Dow Jones News article cited in Paragraph 168 of the Complaint are the best evidence of their contents. The remaining allegations are directed at other defendants and require no response from GSK. To the extent an answer is deemed to be required, GSK denies the remaining allegations in Paragraph 168 and demands strict proof thereof.
  - 169. GSK denies the allegations set forth in Paragraph 169.
- 170-171. GSK states that the April 2003 OIG report cited in Paragraphs 170 through 171 of the Complaint is the best evidence of its content. GSK denies that Plaintiff has accurately characterized any alleged OIG finding, opinion, statement or conclusion, or that such are applicable to GSK.
  - 172. GSK denies the allegations set forth in Paragraph 172.

#### VII. THE AWP INFLATION SCHEME

- 173. GSK denies the allegations set forth in Paragraph 173.
- 174. GSK denies the allegations set forth in Paragraph 174.
- 175. GSK denies the allegations set forth in Paragraph 175.

- 176. GSK admits that it has provided certain list prices to various commercial pricing compendia and believes that those compendia consider the information provided by GSK when publishing AWPs for GSK's products. To the extent the allegations in Paragraph 176 refer to the knowledge, conduct or actions of or benefits received by persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Otherwise, the allegations set forth in Paragraph 176 are denied.
  - 177. GSK denies the allegations set forth in Paragraph 177.
  - 178. GSK denies the allegations set forth in Paragraph 178.
  - 179. GSK denies the allegations set forth in Paragraph 179.
  - 180. GSK denies the allegations set forth in Paragraph 180.
  - 181. GSK denies the allegations set forth in Paragraph 181.
  - 182. GSK denies the allegations set forth in Paragraph 182.
  - 183. GSK denies the allegations set forth in Paragraph 183.
  - 184. GSK denies the allegations set forth in Paragraph 184.
- 185-200. The allegations set forth in Paragraphs 185 through 200 are directed at other defendants and no response from GSK is required. To the extent an answer is deemed to be required, GSK denies the allegations set forth in paragraphs 185 through 200.
- 201. To the extent the allegations in Paragraph 201 refer to the knowledge, conduct or actions of or benefits received by persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.

202. GSK admits the allegations in Paragraph 202 of the Complaint, except denies knowledge or information sufficient to form a belief as to the truth of the allegations in the last sentence of the Paragraph.

203-208. GSK denies the allegations set forth in Paragraphs 203 through 208 that pertain to it. To the extent the allegations in Paragraphs 203 through 208 refer to the knowledge, conduct or actions of or benefits received by persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.

- 209. GSK denies the allegations set forth in Paragraph 209 that pertain to it. To the extent the allegations in Paragraph 209 refer to the knowledge, conduct or actions of or benefits received by persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. GSK states that THE "WALL STREET JOURNAL" article cited in Paragraph 209 of the Complaint is the best evidence of its content. GSK denies that Plaintiff characterized the content of THE WALL STREET JOURNAL article accurately and specifically denies the content of the allegations referencing the article.
- 210. GSK denies the allegations set forth in Paragraph 210 of the Complaint that pertain to it. To the extent the allegations in Paragraph 210 refer to the knowledge, conduct or actions of or benefits received by persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.
- 211-212. GSK denies the existence of, and its participation in, any "scheme" as alleged in Paragraph 211 of the Complaint. GSK states that the September 28, 2000, letter from

Congressman Stark to the President of Pharmaceutical Research and Manufacturers of America cited in Paragraphs 211 through 212 of the Complaint is the best evidence of its contents. GSK denies that Plaintiff has accurately characterized the findings, opinions, statements or conclusions of Congressman Stark, or that such are applicable to GSK.

- 213. To the extent the allegations in Paragraph 213 refer to the knowledge, conduct or actions of or benefits received by persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.
- 214. GSK denies the allegations set forth in Paragraph 214 of the Complaint pertaining to it. To the extent the allegations in Paragraph 214 refer to the knowledge, conduct or actions of or benefits received by persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.
- 215. GSK denies the allegations set forth in Paragraph 215 of the Complaint pertaining to it. To the extent the allegations in Paragraph 215 refer to the knowledge, conduct or actions of or benefits received by persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.
- 216-422. The allegations in Paragraphs 216 through 422 of the Complaint are directed to other defendants and require no response from GSK. To the extent allegations in Paragraphs 216 through 422 of the Complaint are deemed to include allegations against GSK, they are denied.
  - 423. GSK denies the allegations in Paragraph 423 of the Complaint.

- 424. In response to the allegations of Paragraph 424 of the Complaint, GSK admits only that Plaintiff seeks relief as described, but denies that Plaintiff is entitled to such relief, and denies that GSK is in any way liable to Plaintiff. Except as so admitted, GSK denies the remaining allegations of this Paragraph.
- 425. GSK denies the allegations of Paragraph 425 of the Complaint. It is specifically denied that the document referred to in this Paragraph was prepared by Glaxo Wellcome, Inc. To the extent the allegations in this Paragraph refer to a document, that document speaks for itself. Any allegations inconsistent with the plain meaning and clear terms of the complete document are denied.
  - 426. GSK denies the allegations of Paragraph 426 of the Complaint.
- 427. In response to the allegations of Paragraph 427 of the Complaint, GSK admits only that Medicare, Medicaid, and some private insurers reimburse for prescription drugs based on some percentage of the AWP reported by third-party publishing services, such as First DataBank Inc. and Facts and Comparisons. Except as so admitted, GSK denies the remaining allegations of this Paragraph. To the extent the allegations in this Paragraph refer to a document, that document speaks for itself. Any allegations inconsistent with the plain meaning and clear terms of the complete document are denied.
- 428. In response to the allegations of Paragraph 428 of the Complaint, GSK admits only that Medicare, Medicaid, and some private insurers reimburse for prescription drugs based on some percentage of the AWP reported by third-party publishing services, such as First DataBank Inc. and Facts and Comparisons. Except as so admitted, GSK denies the remaining allegations of this Paragraph. It is specifically denied that the document referred to in this Paragraph was prepared by Glaxo Wellcome, Inc. To the extent the allegations in this Paragraph

refer to a document, that document speaks for itself. Any allegations inconsistent with the plain meaning and clear terms of the complete document are denied.

- 429. GSK denies the allegations of Paragraph 429 of the Complaint. To the extent the allegations in this Paragraph refer to a document, that document speaks for itself. Any allegations inconsistent with the plain meaning and clear terms of the complete document are denied.
  - 430. GSK denies the allegations of Paragraph 430 of the Complaint.
- 431. In response to the allegations of Paragraph 431 of the Complaint, GSK admits that Zofran and Kytril are both antiemetics prescribed by physicians for chemotherapy-induced nausea and vomiting. GSK further admits that Zofran and Kytril, although not therapeutically equivalent products as that term is used by the FDA, were and are competing antiemetics. GSK states that Kytril was sold to Hoffman-LaRoche, Inc. in December 22, 2000. Except as so admitted, GSK denies the remaining allegations of this Paragraph.
- 432. GSK denies the allegations of Paragraph 432 of the Complaint. To the extent the allegations in this Paragraph refer to a document, that document speaks for itself. Any allegations inconsistent with the plain meaning and clear terms of the complete document are denied.
- 433. To the extent the allegations of Paragraph 433 of the Complaint refer to a document, that document speaks for itself. Any allegations inconsistent with the plain meaning and clear terms of the complete document are denied.
- 434. GSK denies the allegations of Paragraph 434 of the Complaint. To the extent the allegations in this Paragraph refer to a document, that document speaks for itself. Any

allegations inconsistent with the plain meaning and clear terms of the complete document are denied.

- 435. GSK denies the allegations of Paragraph 435 of the Complaint. To the extent the allegations in this Paragraph refer to a document, that document speaks for itself. Any allegations inconsistent with the plain meaning and clear terms of the complete document are denied.
- 436. GSK denies the allegations of Paragraph 436 of the Complaint. To the extent the allegations in this Paragraph refer to a document, that document speaks for itself. Any allegations inconsistent with the plain meaning and clear terms of the complete document are denied.
- 437. GSK denies the allegations of Paragraph 437 of the Complaint. To the extent the allegations in this Paragraph refer to a document, that document speaks for itself. Any allegations inconsistent with the plain meaning and clear terms of the complete document are denied.
- 438. GSK denies the allegations of Paragraph 438 of the Complaint. To the extent the allegations in this Paragraph refer to a document, that document speaks for itself. Any allegations inconsistent with the plain meaning and clear terms of the complete document are denied.
- 439. GSK denies the allegations of Paragraph 439 of the Complaint. To the extent the allegations in this Paragraph refer to a document, that document speaks for itself. Any allegations inconsistent with the plain meaning and clear terms of the complete document are denied.

- 440. In response to the allegations of Paragraph 440 of the Complaint, GSK admits only that, in March 1996, Glaxo Wellcome, Inc. increased its Net Wholesale Price (NWP) and Average Wholesale Price (AWP) for Zofran by 4.9% for NDCs 00173-0442-00 and 00173-0461-00 and by 8.6% for NDC 00173-0442-02, and SmithKline Beecham Corporation increased its Wholesale Purchase Price (WPP) and Suggested List Price (SLP) for Kytril by 4.8%. Except as so admitted, GSK denies the remaining allegations of this Paragraph. To the extent the allegations in this Paragraph refer to a document, that document speaks for itself. Any allegations inconsistent with the plain meaning and clear terms of the complete document are denied.
- 441. GSK denies the allegations of Paragraph 441 of the Complaint. To the extent the allegations in this Paragraph refer to a document, that document speaks for itself. Any allegations inconsistent with the plain meaning and clear terms of the complete document are denied.
- 442. GSK denies the allegations of Paragraph 442 of the Complaint. It is specifically denied that the document referred to in this paragraph was prepared by Glaxo Wellcome, Inc. To the extent the allegations in this Paragraph refer to a document, that document speaks for itself. Any allegations inconsistent with the plain meaning and clear terms of the complete document are denied.
- 443. GSK denies the allegations of Paragraph 443 of the Complaint. It is specifically denied that the documents referred to in this Paragraph were prepared by Glaxo Wellcome, Inc. To the extent the allegations in this Paragraph refer to documents, those documents speak for themselves. Any allegations inconsistent with the plain meaning and clear terms of the complete documents are denied.

- 444. GSK denies the allegations of Paragraph 444 of the Complaint. To the extent the allegations in this Paragraph refer to a document, that document speaks for itself. Any allegations inconsistent with the plain meaning and clear terms of the complete document are denied.
- 445. GSK denies the allegations of Paragraph 445 of the Complaint. To the extent the allegations in this Paragraph refer to a document, that document speaks for itself. Any allegations inconsistent with the plain meaning and clear terms of the complete document are denied.
- 446. GSK denies the allegations of Paragraph 446 of the Complaint. To the extent the allegations in this Paragraph refer to a document, that document speaks for itself. Any allegations inconsistent with the plain meaning and clear terms of the complete document are denied.
- 447. GSK denies the allegations of Paragraph 447 of the Complaint. To the extent the allegations in this Paragraph refer to a document, that document speaks for itself. Any allegations inconsistent with the plain meaning and clear terms of the complete document are denied.
- 448. In response to the allegations of Paragraph 448 of the Complaint, GSK admits only that Kytril was sold to Hoffman-LaRoche, Inc. in December 22, 2000. Except as so admitted, GSK denies the remaining allegations of this Paragraph. To the extent the allegations in this Paragraph refer to a document, that document speaks for itself. Any allegations inconsistent with the plain meaning and clear terms of the complete document are denied.
- 449. GSK denies the allegations of Paragraph 449 of the Complaint. To the extent the allegations in this Paragraph refer to a document, that document speaks for itself. Any

allegations inconsistent with the plain meaning and clear terms of the complete document are denied.

- 450. GSK denies the allegations of Paragraph 450 of the Complaint. To the extent the allegations in this Paragraph refer to documents, those documents speak for themselves. Any allegations inconsistent with the plain meaning and clear terms of the complete documents are denied.
  - 451. GSK denies the allegations of Paragraph 451 of the Complaint.
- 452. To the extent the allegations of Paragraph 452 of the Complaint refer to a document, that document speaks for itself. Any allegations inconsistent with the plain meaning and clear terms of the complete document are denied.
- 453. GSK denies the allegations of Paragraph 453 of the Complaint. To the extent the allegations in this Paragraph refer to a document, that document speaks for itself. Any allegations inconsistent with the plain meaning and clear terms of the complete document are denied.
- 454. GSK denies the allegations of Paragraph 454 of the Complaint. To the extent the allegations in this Paragraph refer to a document, that document speaks for itself. Any allegations inconsistent with the plain meaning and clear terms of the complete document are denied.
  - 455. GSK denies the allegations of Paragraph 455 of the Complaint.
  - 456. GSK denies the allegations of Paragraph 456 of the Complaint.
  - 457. GSK denies the allegations of Paragraph 457 of the Complaint.
- 458. GSK denies the allegations of Paragraph 458 of the Complaint. To the extent the allegations in this Paragraph refer to a document, that document speaks for itself. Any

allegations inconsistent with the plain meaning and clear terms of the complete document are denied.

- 459. GSK denies the allegations of Paragraph 459 of the Complaint. To the extent the allegations in this Paragraph refer to a document, that document speaks for itself. Any allegations inconsistent with the plain meaning and clear terms of the complete document are denied.
- 460. In response to the allegations of Paragraph 460 of the Complaint, GSK admits that Kytril was effective when dosed based on the weight of the patient and, as a result, in some cases, physicians may have used less than 1 mg of the single dose vial. GSK further admits that, beginning in July 1997, it manufactured and sold a 4 mg multi-dose vial of Kytril. Except as so admitted, GSK denies the remaining allegations of this Paragraph. To the extent the allegations in this Paragraph refer to a document, that document speaks for itself. Any allegations inconsistent with the plain meaning and clear terms of the complete document are denied.
  - 461. GSK denies the allegations of Paragraph 461 of the Complaint.
- 462. In response to the allegations of Paragraph 462 of the Complaint, GSK admits only that, in response to subpoenas and/or requests for information, it has provided documents and/or information with respect to certain products to the United States Department of Justice, the Office of Inspector General of the Department of Health and Human Services, the Attorney General for Texas, and the Attorney General for California. Except as so admitted, GSK denies the remaining allegations of this Paragraph.
  - 463. GSK denies the allegations of Paragraph 463 of the Complaint.
- 464. GSK denies the allegations of Paragraph 464 of the Complaint. To the extent the allegations in this Paragraph refer to a report by the Department of Health and Human Services,

that report speaks for itself. Any allegations inconsistent with the plain meaning and clear terms of the report are denied. It is specifically denied that the table in this Paragraph and/or the report by the Department of Health and Human Services accurately calculated the AWP, the "actual AWP," the "difference," and/or the "percentage spread."

465-602. The allegations in Paragraphs 465 through 602 of the Complaint are directed to another defendant and require no response from GSK. To the extent allegations in Paragraphs 465 through 602 of the Complaint are deemed to include allegations against GSK, they are denied.

#### VIII. <u>DEFENDANTS' "BEST PRICE" FRAUDS</u>

603-609. The allegations in Paragraphs 603 through 609 of the Complaint attempt to summarize statutes and regulations applicable to the Medicaid Rebate Program and therefore constitute legal conclusions to which no response is required. Pursuant to the Court's June 10, 2004 Order, all of Plaintiff's "Best Price" claims against GSK have been dismissed except those relating to Flonase and Paxil, as referenced in Paragraphs 617 through 620 of the Complaint. Those claims have been specifically released by Plaintiff in a separate Settlement Agreement and Release. Therefore, Plaintiff has no remaining "Best Price" claims against GSK in this Complaint.

and are the best evidence of their contents. Pursuant to the Court's June 10, 2004 Order, all of Plaintiff's "Best Price" claims against GSK have been dismissed except those relating to Flonase and Paxil, as referenced in Paragraphs 617 through 620 of the Complaint. Those claims have been specifically released by Plaintiff in a separate Settlement Agreement and Release. Therefore, Plaintiff has no remaining "Best Price" claims against GSK in this Complaint.

- 612. GSK denies the allegations in Paragraph 612 of the Complaint that pertain to it. To the extent the allegations in Paragraph 612 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Pursuant to the Court's June 10, 2004 Order, all of Plaintiff's "Best Price" claims against GSK have been dismissed except those relating to Flonase and Paxil, as referenced in Paragraphs 617 through 620 of the Complaint. Those claims have been specifically released by Plaintiff in a separate Settlement Agreement and Release. Therefore, Plaintiff has no remaining "Best Price" claims against GSK in this Complaint.
- 613. GSK denies the allegations in Paragraph 613 of the Complaint. Pursuant to the Court's June 10, 2004 Order, all of Plaintiff's "Best Price" claims against GSK have been dismissed except those relating to Flonase and Paxil, as referenced in Paragraphs 617 through 620 of the Complaint. Those claims have been specifically released by Plaintiff in a separate Settlement Agreement and Release. Therefore, Plaintiff has no remaining "Best Price" claims against GSK in this Complaint.
- 614. GSK denies the allegations in Paragraph 614 of the Complaint to the extent they imply that GSK engaged in any wrongdoing or acted improperly with respect to the Medicaid Rebate Program. As to the remaining allegations in this Paragraph, the document referenced in the Paragraph speaks for itself and is the best evidence of its contents. Pursuant to the Court's June 10, 2004 Order, all of Plaintiff's "Best Price" claims against GSK have been dismissed except those relating to Flonase and Paxil, as referenced in Paragraphs 617 through 620 of the Complaint. Those claims have been specifically released by Plaintiff in a separate Settlement

Agreement and Release. Therefore, Plaintiff has no remaining "Best Price" claims against GSK in this Complaint.

- 615. GSK denies the allegations in Paragraph 615 of the Complaint that pertain to it. To the extent the allegations in Paragraph 615 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. Pursuant to the Court's June 10, 2004 Order, all of Plaintiff's "Best Price" claims against GSK have been dismissed except those relating to Flonase and Paxil, as referenced in Paragraphs 617 through 620 of the Complaint. Those claims have been specifically released by Plaintiff in a separate Settlement Agreement and Release. Therefore, Plaintiff has no remaining "Best Price" claims against GSK in this Complaint.
- 616. GSK denies the allegations in Paragraph 616 of the Complaint. Pursuant to the Court's June 10, 2004 Order, all of Plaintiff's "Best Price" claims against GSK have been dismissed except those relating to Flonase and Paxil, as referenced in Paragraphs 617 through 620 of the Complaint. Those claims have been specifically released by Plaintiff in a separate Settlement Agreement and Release. Therefore, Plaintiff has no remaining "Best Price" claims against GSK in this Complaint.
- 617. GSK admits that it agreed to pay \$87,600,922 to the United States, the States (including Plaintiff) and various PHS entities to settle potential claims, with no admission of wrongdoing by GSK, relating to Medicaid rebates for Flonase and Paxil as set forth in the Settlement Agreements entered into by GSK, the United States and the States. GSK denies the remaining allegations in Paragraph 617 of the Complaint. Pursuant to the Court's June 10, 2004 Order, all of Plaintiff's "Best Price" claims against GSK have been dismissed except those

relating to Flonase and Paxil, as referenced in Paragraphs 617 through 620 of the Complaint. Those claims have been specifically released by Plaintiff in a separate Settlement Agreement and Release. Therefore, Plaintiff has no remaining "Best Price" claims against GSK in this Complaint.

- 618. GSK admits that it manufactured, packaged and shipped Flonase and Paxil to Kaiser Permanente, an HMO with offices in California. GSK denies the remaining allegations in Paragraph 618 of the Complaint. Pursuant to the Court's June 10, 2004 Order, all of Plaintiff's "Best Price" claims against GSK have been dismissed except those relating to Flonase and Paxil, as referenced in Paragraphs 617 through 620 of the Complaint. Those claims have been specifically released by Plaintiff in a separate Settlement Agreement and Release. Therefore, Plaintiff has no remaining "Best Price" claims against GSK in this Complaint.
- 619. GSK denies the allegations in Paragraph 619 of the Complaint. Pursuant to the Court's June 10, 2004 Order, all of Plaintiff's "Best Price" claims against GSK have been dismissed except those relating to Flonase and Paxil, as referenced in Paragraphs 617 through 620 of the Complaint. Those claims have been specifically released by Plaintiff in a separate Settlement Agreement and Release. Therefore, Plaintiff has no remaining "Best Price" claims against GSK in this Complaint.
- 620. GSK admits that the periods of time for which it settled with the United States, the States (including Plaintiff) and the PHS entities are First Quarter 1997 through First Quarter 2000 for Flonase and Third Quarter 2000 for Paxil. GSK denies the remaining allegations in Paragraph 620 of the Complaint. Pursuant to the Court's June 10, 2004 Order, all of Plaintiff's "Best Price" claims against GSK have been dismissed except those relating to Flonase and Paxil, as referenced in Paragraphs 617 through 620 of the Complaint. Those claims have been

specifically released by Plaintiff in a separate Settlement Agreement and Release. Therefore, Plaintiff has no remaining "Best Price" claims against GSK in this Complaint.

621-634. The allegations in Paragraphs 621 through 634 of the Complaint are directed to other defendants and require no response from GSK. To the extent allegations in Paragraphs 621 through 634 of the Complaint are deemed to include allegations against GSK, they are denied.

### IX. <u>DEFENDANTS' CONCEALMENT OF THE TRUTH AND</u> <u>TOLLING OF STATUTES OF LIMITATION</u>

- 635. GSK denies the allegations set forth in Paragraph 635 of the Complaint that pertain to it. To the extent the allegations in Paragraph 635 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.
- 636. GSK denies the allegations set forth in Paragraph 636 of the Complaint that pertain to it. To the extent the allegations in Paragraph 636 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. GSK states that the 2003 CMS document cited in Paragraph 636 of the Complaint is the best evidence of its contents. GSK denies that Plaintiff has accurately characterized any alleged CMS finding, opinion, statement or conclusion. GSK admits that it sells its medicines in a competitive market and, as such, takes steps to keep certain information relating to its medicines confidential.
- 637-640. GSK denies the allegations in Paragraphs 637 through 640 of the Complaint that pertain to it. To the extent the allegations in Paragraphs 637 through 640 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than GSK,

GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.

641. In response to the allegations in Paragraph 641 of the Complaint, GSK denies that Plaintiff lacked inquiry or other notice of the issues associated with reliance on AWPs as a pricing benchmark. GSK specifically avers, to the contrary, that such issues were well known for more than a decade before Plaintiff elected to bring this suit.

642-643. The allegations in Paragraphs 642 through 643 of the Complaint state legal conclusions to which no response is required. To the extent a response is required, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations in Paragraphs 642 through 643 of the Complaint that refer to the knowledge, conduct or actions of persons, entities or defendants other than GSK. Accordingly, GSK denies those allegations. GSK denies the remaining allegations in Paragraphs 642 through 643 of the Complaint that pertain to it.

### X. <u>DIRECT DAMAGE SUSTAINED BY THE STATE OF MONTANA</u>, <u>PATIENTS AND THIRD-PARTY PAYORS</u>

- 644. GSK denies the allegations set forth in Paragraph 644.
- 645. GSK admits it is aware that Medicare beneficiaries are generally responsible, but not necessarily required, to pay a 20 percent co-payment. To the extent the allegations refer to statutes, regulations or other documents, those sources speak for themselves and are the best evidence of their contents. Any characterizations are denied. To the extent the allegations in Paragraph 645 set forth legal arguments or conclusions of law, no response is required and none is made. GSK denies the remaining allegations in Paragraph 645 of the Complaint that pertain to it.

- 646. The allegations in Paragraph 646 contain Plaintiff's generalizations and self-serving conclusions. Accordingly, no answer is required and none is made. To the extent an answer is deemed to be required, the allegations are denied and strict proof is demanded thereof.
- 647. GSK denies the allegations set forth in Paragraph 647 of the Complaint that pertain to it. To the extent the allegations in Paragraph 647 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.
- 648. GSK denies the allegations set forth in Paragraph 648 of the Complaint that pertain to it. To the extent the allegations in Paragraph 648 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.
- 649. GSK denies the allegations set forth in Paragraph 649 of the Complaint that pertain to it. To the extent the allegations in Paragraph 649 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.
- 650. GSK denies the allegations set forth in Paragraph 650 of the Complaint that pertain to it.
- 651. Pursuant to the Court's June 10, 2004 Order, all of Plaintiff's "Best Price" claims against GSK have been dismissed except those relating to Flonase and Paxil, as referenced in Paragraphs 617 through 620 of the Complaint. Those claims have been specifically released by

Plaintiff in a separate Settlement Agreement and Release. Therefore, Plaintiff has no remaining "Best Price" claims against GSK in this Complaint.

- 652. GSK denies the allegations set forth in Paragraph 652 of the Complaint that pertain to it.
- 653. GSK denies the allegations set forth in Paragraph 653 of the Complaint that pertain to it.

#### XI. CLAIMS FOR RELIEF

#### COUNT I

### <u>Deceptive Trade Practices:</u> <u>Claim for Damages Caused to Montana Residents</u>

- 654. GSK realleges and incorporates its responses to the allegations in Paragraphs 1 through 653.
- 655. The allegations set forth in Paragraph 655 contain Plaintiff's characterization of this action. No response is required and none is made.
- 656. GSK denies the allegations set forth in Paragraph 656 of the Complaint that pertain to it. To the extent the allegations in Paragraph 656 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. To the extent the allegations refer to statutes, regulations or other documents, those sources speak for themselves and are the best evidence of their contents. Any characterizations thereof are denied. To the extent the allegations in Paragraph 656 set forth legal arguments or conclusions of law, no response is required and none is made.
- 657. GSK denies the allegations set forth in Paragraph 657 of the Complaint that pertain to it. To the extent the allegations in Paragraph 657 of the Complaint refer to the

knowledge, conduct or actions of persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.

- 658. GSK denies the allegations set forth in Paragraph 658 of the Complaint that pertain to it. To the extent the allegations in Paragraph 658 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.
- 659. GSK denies the allegations set forth in Paragraph 659 of the Complaint that pertain to it. To the extent the allegations in Paragraph 659 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.
- 660. GSK denies the allegations set forth in Paragraph 660 of the Complaint that pertain to it. To the extent the allegations in Paragraph 660 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.

GSK denies Plaintiff is entitled to a judgment or any other relief requested in the Prayer for Relief for Count I of the Complaint.

#### **COUNT II**

## <u>Deceptive Trade Practices:</u> <u>Claim for Civil Penalties, Injunctive Relief, and</u> Restitution for the State of Montana

- 661. GSK realleges and incorporates its responses to the allegations in Paragraphs 1 through 660.
- 662. The allegations set forth in Paragraph 662 contain Plaintiff's characterization of this action. No response is required and none is made. To the extent the allegations relate to Plaintiff's "Best Price" claims against GSK, those claims have been dismissed pursuant to the Court's June 10, 2004 Order, except those claims relating to Flonase and Paxil, as referenced in Paragraphs 617 through 620 of the Complaint. Those claims have been specifically released by Plaintiff in a separate Settlement Agreement and Release. Therefore, Plaintiff has no remaining "Best Price" claims against GSK.
- 663. GSK denies the allegations set forth in Paragraph 663 of the Complaint that pertain to it. To the extent the allegations in Paragraph 663 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. To the extent the allegations refer to statutes, regulations or other documents, those sources speak for themselves and are the best evidence of their contents. Any characterizations thereof are denied. To the extent the allegations in Paragraph 663 set forth legal arguments or conclusions of law, no response is required and none is made. To the extent the allegations relate to Plaintiff's "Best Price" claims against GSK, those claims have been dismissed pursuant to the Court's June 10, 2004 Order, except those claims relating to Flonase and Paxil, as referenced in Paragraphs 617 through 620 of the Complaint. Those claims have

been specifically released by Plaintiff in a separate Settlement Agreement and Release.

Therefore, Plaintiff has no remaining "Best Price" claims against GSK.

- 664. GSK denies the allegations set forth in Paragraph 664 of the Complaint that pertain to it. To the extent the allegations in Paragraph 664 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. To the extent the allegations relate to Plaintiff's "Best Price" claims against GSK, those claims have been dismissed pursuant to the Court's June 10, 2004 Order, except those claims relating to Flonase and Paxil, as referenced in Paragraphs 617 through 620 of the Complaint. Those claims have been specifically released by Plaintiff in a separate Settlement Agreement and Release. Therefore, Plaintiff has no remaining "Best Price" claims against GSK.
- 665. GSK denies the allegations set forth in Paragraph 665 of the Complaint that pertain to it. To the extent the allegations in Paragraph 665 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. To the extent the allegations relate to Plaintiff's "Best Price" claims against GSK, those claims have been dismissed pursuant to the Court's June 10, 2004 Order, except those claims relating to Flonase and Paxil, as referenced in Paragraphs 617 through 620 of the Complaint. Those claims have been specifically released by Plaintiff in a separate Settlement Agreement and Release. Therefore, Plaintiff has no remaining "Best Price" claims against GSK.

666. GSK denies the allegations set forth in Paragraph 666 of the Complaint that pertain to it. To the extent the allegations in Paragraph 666 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. To the extent the allegations relate to Plaintiff's "Best Price" claims against GSK, those claims have been dismissed pursuant to the Court's June 10, 2004 Order, except those claims relating to Flonase and Paxil, as referenced in Paragraphs 617 through 620 of the Complaint. Those claims have been specifically released by Plaintiff in a separate Settlement Agreement and Release. Therefore, Plaintiff has no remaining "Best Price" claims against GSK.

667. GSK denies the allegations set forth in Paragraph 667 of the Complaint that pertain to it. To the extent the allegations in Paragraph 667 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations. To the extent the allegations relate to Plaintiff's "Best Price" claims against GSK, those claims have been dismissed pursuant to the Court's June 10, 2004 Order, except those claims relating to Flonase and Paxil, as referenced in Paragraphs 617 through 620 of the Complaint. Those claims have been specifically released by Plaintiff in a separate Settlement Agreement and Release. Therefore, Plaintiff has no remaining "Best Price" claims against GSK.

GSK denies Plaintiff is entitled to a judgment or any other relief requested in the Prayer for Relief for Count II of the Complaint.

# **COUNT III**

# Medicaid Fraud: Claim for Cost Recovery And Civil Penalties

668-679. Plaintiff's "Best Price" claims against GSK have been dismissed pursuant to the Court's June 10, 2004 Order, except those claims relating to Flonase and Paxil, as referenced in Paragraphs 617 through 620 of the Complaint. Those claims have been specifically released by Plaintiff in a separate Settlement Agreement and Release. Therefore, Plaintiff has no remaining "Best Price" claims against GSK.

#### **COUNT IV**

# False Claims: Claim for Forfeiture, Civil Penalties, Double Damages and Legal Costs

dismissed pursuant to the Court's June 10, 2004 Order. Accordingly, no response is required and none is made as to those claims. GSK denies the remaining allegations set forth in Paragraphs 680 through 691 of the Complaint that pertain to it. To the extent the allegations in these Paragraphs refer to the knowledge, conduct or actions of persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.

GSK denies Plaintiff is entitled to a judgment or any other relief requested in the Prayer for Relief for Count IV of the Complaint.

#### **COUNT V**

# Punitive Damages: Claim Brought on Behalf of the State of Montana

- 692. GSK realleges and incorporates its responses to the allegations in Paragraphs 1 through 691.
- 693. GSK denies the allegations set forth in Paragraph 693 of the Complaint that pertain to it. To the extent the allegations in Paragraph 693 of the Complaint refer to the knowledge, conduct or actions of persons, entities or defendants other than GSK, GSK is without knowledge or information sufficient to form a belief as to the truth of those allegations and, therefore, denies those allegations.

GSK denies Plaintiff is entitled to a judgment or any other relief requested in the Prayer for Relief for Count V of the Complaint.

# XI. <u>DEMAND FOR JURY TRIAL</u>

GSK denies Plaintiff is entitled to a judgment or any other relief requested in the Prayer for Relief.

# **DEFENSES**

#### First Defense

Plaintiff fails to state a claim against GSK upon which relief may be granted.

# **Second Defense**

Some or all of Plaintiff's claims are barred, in whole or in part, by the political question and separation of powers doctrines.

# **Third Defense**

Plaintiff has not suffered, and will not suffer, any injury to a legally protected or cognizable interest by reason of the conduct of GSK as alleged in the Complaint.

#### **Fourth Defense**

To the extent Plaintiff or any of its citizens for whom it is seeking relief obtains recovery in any other case predicated on the same factual allegations, it is barred from seeking recovery against GSK based on the Complaint pursuant to the doctrines of res judicata and collateral estoppel and the prohibition on double recovery for the same injury.

#### **Fifth Defense**

Plaintiff's claims are barred, in whole or in part, by the First Amendment to the United States Constitution and the analogous provisions of the Constitution of the State of Montana.

## Sixth Defense

Plaintiff's claims are barred, in whole or in part, to the extent that Plaintiff or any of its citizens for whom it is seeking relief has released, settled, entered into an accord and satisfaction or otherwise compromised its claims.

# **Seventh Defense**

Any and all actions taken by GSK with respect to any of the matters alleged in the Complaint were taken in good faith and in accordance with established industry practice.

#### **Eighth Defense**

Plaintiff's state law claims are preempted, in whole or in part, by federal law, including without limitation, the Federal Employment Retirement Income and Security Act of 1974, the Federal Medicare Act, and the Federal Medicaid Act, including all amendments to the same and all regulations promulgated thereunder.

# Ninth Defense

Plaintiff's claims are preempted by the dormant Commerce Clause of the United States Constitution.

#### **Tenth Defense**

Plaintiff's claims against GSK are barred because GSK has complied with all applicable regulations of the federal and state governments.

# **Eleventh Defense**

Plaintiff's claims against GSK are barred, in whole or in part, by the applicable statutes of limitations and repose, and by the doctrines of laches, estoppel and waiver.

#### **Twelfth Defense**

Plaintiff's claims are barred, in whole or in part, because they violate GSK's rights under the Due Process and Ex Post Facto clauses of the United States Constitution, as well as the Constitution of the State of Montana, insofar as Plaintiff seeks to impose liability retroactively for conduct that was not actionable at the time it occurred.

# **Thirteenth Defense**

GSK's statements or actions were not the proximate cause or cause in fact of any injury or alleged loss.

# Fourteenth Defense

Plaintiff fails to state with particularity facts to support the fraud allegations, and fails to plead with particularity the fraudulent concealment and multi-source medicine allegations against GSK contained in the Complaint.

# Fifteenth Defense

Plaintiff has no standing or capacity to bring some or all of the claims raised in this suit, including, but not limited to, Plaintiff's asserted status in *parens patriae* to recover Medicaid or Medicare expenditures or to seek injunctive relief.

#### **Sixteenth Defense**

Plaintiff fails to allege with particularity its civil conspiracy claims against GSK as required by FED. R. CIV. P. 9(b).

#### **Seventeenth Defense**

Plaintiff's claims against GSK are barred because GSK did not directly or indirectly conspire with any other entity or engage in any other conduct in violation of state or federal law.

#### **Eighteenth Defense**

Plaintiff's claims against GSK are barred, in whole or in part, because GSK did not make any false statements to Plaintiff or any of the citizens for whom Plaintiff is seeking relief. As to any statement asserted against GSK that Plaintiff alleges to be false or misleading, GSK had no

reasonable grounds to believe, and did not believe at the time such a statement was made, that the statement was false or misleading.

# **Nineteenth Defense**

Plaintiff's claims against GSK are barred because GSK did not directly or indirectly engage in any conduct in violation of state or federal law.

#### **Twentieth Defense**

GSK denies that Plaintiff has valid consumer protection claims against GSK under Montana state law. However, if such claims are found to exist, GSK pleads all available defenses under the applicable laws.

# **Twenty-First Defense**

Any allegedly fraudulent statements or conduct of GSK did not directly or proximately cause the alleged injuries as required under state consumer protection laws of Montana.

# **Twenty-Second Defense**

GSK's conduct was not "deceptive" as required under Montana consumer protection laws.

#### **Twenty-Third Defense**

To the extent that Plaintiff seeks equitable relief against GSK, Plaintiff is not entitled to such relief because there is an adequate remedy at law.

# **Twenty-Fourth Defense**

Plaintiff did not rely on the allegedly fraudulent statements or conduct of GSK as required under the Montana consumer protection laws.

# **Twenty-Fifth Defense**

Any allegedly fraudulent statement or conduct of GSK was not consumer-oriented as required under the Montana consumer protection laws.

#### **Twenty-Sixth Defense**

Plaintiff's claims against GSK for injunctive relief were mooted by the passage of the 2003 Medicare reform legislation.

#### **Twenty-Seventh Defense**

Some or all of Plaintiff's claims for injunctive relief against GSK are barred by the doctrines of *in pari delicto* and/or unclean hands.

#### **Twenty-Eighth Defense**

Some or all of Plaintiff's claims against GSK arise from Plaintiff's failure to follow its federal and state statutory and regulatory obligation to set reimbursement rates at Estimated Acquisition Cost.

# **Twenty-Ninth Defense**

Plaintiff's claims against GSK are barred, in whole or in part, due to it failure to join indispensable parties.

# **Thirtieth Defense**

Plaintiff's claims against GSK are barred, in whole or in part, because it suffered no damages as a result of the matters alleged in the Complaint.

#### **Thirty-First Defense**

Plaintiff's claims are barred, in whole or in part, because any injuries sustained by Plaintiff were the result of its own conduct or the intervening or superseding conduct of third parties.

#### **Thirty-Second Defense**

Plaintiff's claims against GSK for damages are barred, in whole or in part, because:

(1) Plaintiff failed to mitigate its damages, and that failure to mitigate damages should proportionately reduce the recovery of such persons and the allocation of any fault, if any exists,

attributable to GSK; (2) Plaintiff would be unjustly enriched if allowed to recover any portion of the damages alleged in the Complaint; (3) by the doctrine of consent and/or ratification to the extent that Plaintiff has received and paid for medicines manufactured, marketed and sold by GSK after the filing of Plaintiff's original Complaint; and (4) Plaintiff's claims are speculative and remote and because of the impossibility of ascertaining and allocating those alleged damages.

#### **Thirty-Third Defense**

GSK is entitled to a set-off, should any damages be awarded against it, for the entire amount of all damages or settlement amounts recovered by Plaintiff, with respect to the same alleged injuries.

# **Thirty-Fourth Defense**

The applicable statutory ceilings on recoverable damages must limit any damages recovered by Plaintiff from GSK.

#### **Thirty-Fifth Defense**

Plaintiff fails to allege facts or a cause of action against GSK sufficient to support a claim for attorneys' fees, double damages and/or legal fees.

#### **Thirty-Sixth Defense**

Plaintiff's punitive damages claims against GSK: (1) have no basis in law or fact; (2) are not recoverable because the allegations of the Complaint are legally insufficient to support a claim for punitive damages against GSK; (3) cannot be sustained because laws regarding the standards for determining liability for and the amount of punitive damages fail to give GSK prior notice of the conduct for which punitive damages may be imposed and the severity of the penalty that may be imposed and are void for vagueness in violation of GSK's due process rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and the

Constitution of the State of Montana; (4) cannot be sustained because any award of punitive damages exceeding the limits authorized by the laws or other comparable laws would violate GSK's due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would be improper under the Constitution, common law and applicable state laws of Montana; (5) cannot be sustained because an award of punitive damages in this case, combined with any prior, contemporaneous, or subsequent judgments against GSK for punitive damages arising from the design, development, manufacture, fabrication, distribution, supply, marketing, sale, or use of GSK's medicines, would constitute impermissible multiple punishments for the same wrong in violation of GSK's due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would constitute double jeopardy in violation of the Constitution, common law and statutory law of Montana; (6) cannot be sustained because any award of punitive damages without the apportionment of the award separately and severally between or among the alleged joint tortfeasors, as determined by the alleged percentage of the wrong committed by each alleged tortfeasor, would violate GSK's due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would be improper under the Constitution, common law and public policies of Montana; and (7) cannot be sustained because any award of punitive damages, which are penal in nature, without according GSK the same protections that are accorded to all criminal defendants, including the protection against unreasonable searches and seizures, the privilege against selfincrimination, and the rights to confront adverse witnesses, a speedy trial, and the effective assistance of counsel, would violate GSK's rights guaranteed by the Fourth, Fifth, and Sixth

Amendments as incorporated into the Fourteenth Amendment to the United States Constitution and would be improper under the Constitution, common law and public policies of Montana.

#### **Thirty-Seventh Defense**

Plaintiff's claim for punitive damages against GSK cannot be sustained because an award of punitive damages by a jury that: (1) is not provided constitutionally adequate standards of sufficient clarity for determining the appropriate imposition of, and the appropriate size of, a punitive damages award; (2) is not adequately instructed on the limits of punitive damages imposed by the applicable principles of deterrence and punishment; (3) is not expressly prohibited from awarding punitive damages, or determining the amount of an award of punitive damages, in whole or in part, on the basis of invidiously discriminatory characteristics, including without limitation, the residence, wealth, and corporate status of GSK; (4) is permitted to award punitive damages under a standard for determining liability for punitive damages that is vague and arbitrary and does not define with sufficient clarity the conduct or mental state that makes punitive damages permissible; (5) is not properly instructed regarding Plaintiff's burden of proof with respect to each and every element of a claim for punitive damages; and (6) is not subject to trial court and appellate judicial review for reasonableness and furtherance of legitimate purposes on the basis of constitutionally adequate and objective standards, would violate GSK's Due Process and Equal Protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution, and would be improper under the Constitution, common law and public policies of Montana.

#### **Thirty-Eighth Defense**

Plaintiff's claim for punitive damages against GSK cannot be sustained because an award of punitive damages that is subject to no predetermined limit, such as a maximum multiple of compensatory damages or a maximum amount of punitive damages that may be imposed, would:

(1) violate GSK's Due Process rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution; (2) violate GSK's right not to be subjected to an excessive award; and (3) be improper under the Constitution, common law and public policies of Montana.

# **Thirty-Ninth Defense**

GSK adopts by reference any additional applicable defense pled by any other defendant in this case, not otherwise pled herein.

# Fortieth Defense

GSK hereby gives notice that it intends to rely upon any other and additional defense that is now or may become available or appear during, or as a result of, the discovery proceedings in this action, and hereby reserves its right to amend its answer to assert such defense.

# **Forty-First Defense**

Plaintiff's fraud-based claims and Plaintiff's claims of fraudulent concealment are barred because Plaintiff knew or should have known for more than a decade before the filing of the Complaint that published AWPs do not represent actual averages of the prices at which providers or pharmacies are able to purchase drugs.

WHEREFORE, GSK respectfully demands judgment dismissing the Complaint in its entirety and awarding it the costs and disbursements of this action, as well as such other and further relief as this Court deems just and proper.

DATED: July 12, 2004

Respectfully submitted,

BY: /s/ Seth B. Kosto

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Counsel for SmithKline Beecham Corp. d/b/a GlaxoSmithKline ("GSK")

# **CERTIFICATE OF SERVICE**

I hereby certify that on this 12th day of July, 2004, a true and correct copy of the foregoing document was served upon all counsel of record by electronic service pursuant to CMO No. 2, by causing a copy to be sent to Verilaw Technologies for posting and notification.

/s/
Attorney for Defendant SmithKlineBeecham

Corporation d/b/a GlaxoSmithKline